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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,520	06/06/2001	Phillip R. Hawkins	PF-0059-5 CON	6922

27904 7590 10/02/2002

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EXAMINER
SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/875,520	HAWKINS ET AL.	
	Examiner	Art Unit	
	J. Douglas Schultz	1635	

-- Th MAILING DATE of this communication appears on the cov r she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,24 and 28-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,24 and 28-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1 and 2, drawn to the polypeptide encoded by SEQ ID NO 2, classified in class 930, subclass 10.

II. Claim 24, drawn to a method of screening for molecules that bind to the polypeptide of SEQ ID NO 2, classified in class 435, subclass 7.1.

III. Claim 28, 30, 31, 33, 41, and 42, drawn to antibodies specific for the polypeptide of SEQ ID NO 2, classified in class 530, subclass 387.1.

IV. Claim 29, 32, 34, drawn to methods of diagnosing patients with a disease related to P5CRH, classified in class 435, subclass 4.

V. Claim 35-37, drawn to a method of making a polyclonal antibody against SEQ ID NO. 1 and the resultant polyclonal antibody, classified in class 435, subclass 69.3.

VI. Claim 38-40, drawn to a method of making a monoclonal antibody against SEQ ID NO. 1 and the resultant monoclonal antibody, classified in class 435, subclass 69.3.

VII. Claim 43, drawn to a method of detecting and purifying the polynucleotide sequence of SEQ ID NO. 1, classified in class 435, subclass 23.1.

VIII. Claim 44, drawn to a method of purifying the polynucleotide sequence of SEQ ID NO. 1, classified in class 530, subclass 412.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the inventions listing different sequences are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434)

Groups I-IV specifically claim the polypeptide of SEQ ID NO 2, or uses thereof. Groups V-VIII specifically claim the use of SEQ ID NO 1. The instant sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct because each sequence has a unique nucleotide sequence, and thus each sequence functions differently in the claimed inventions. Furthermore, a search of more than one (1) of the sequences claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect an invention related to one (1) sequence for examination in the instant application.

The inventions are distinct, each from the other because of the following reasons:

Groups I and III are directed to products that are different both physically and functionally, are not required one for the other, and are therefore unrelated. For example, the polypeptide of Group I can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g. in screening). Since

these these compounds don't function together as disclosed, the compounds are materially different. Therefore a search and examination of all these products in one patent application would result in an undue burden, since the searches for the products are not co-extensive, the classification is different, and the subject matter and steps are divergent.

Further, the diagnosis steps of group IV are patentably distinct from the screening method of group II because the steps involved in diagnosing patients are unrelated. In order to diagnose patients, one must identify a patient population, and develop dosage and administration protocols that lead to disease diagnosis. None of these steps are required in the method of screening compounds of group II

The methods of making antibodies of groups V and VI are also unrelated to each other, and also to the methods of detecting or purifying the polynucleotide of SEQ ID NO 1 of group VII, since making antibodies requires in vivo injections, and screening of cells (Group VI) or blood plasma (group V) which are different from each other, and neither of which are involved in the methods of detecting or purifying the polynucleotide of SEQ ID NO 1.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Further, a search and examination of all these products in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter and steps are divergent.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

J. Douglas Schultz
October 1, 2002

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600